

### **REMARKS/ARGUMENTS**

The foregoing amendments in the specification and claims are of a formal nature, and do not add new matter.

Applicants note and appreciate the withdrawal of the earlier objections and rejections under 35 U.S.C. §112, first paragraph, and second paragraph.

Prior to the present amendment, Claims 33-36, 38-40 and 44-54 were pending in this application and were rejected on various grounds. With this amendment, Claims 34-36 have been canceled without prejudice and Claims 33, 46 and 48 have been amended to clarify what applicants have always regarded as their invention.

Claims 33, 38-40 and 44-54 are pending after entry of the instant amendment.

### **Priority Determination**

Applicants note that the effective filing date of the present application is October 29, 1999, the filing date of U.S. Provisional Patent Application Serial No. 60/162,506.

### **Claim Rejections – 35 U.S.C. §112, First Paragraph (Enablement)**

Claims 33-36 and 44-47 stand rejected and new Claims 48-54 are rejected under 35 U.S.C. §112, first paragraph, allegedly because "the specification does not reasonably provide enablement for an isolated nucleic acid encoding the polypeptide of SEQ ID NO:77 or variants of the nucleic acid of SEQ ID NO:76." The Examiner alleges that regarding Claims 48-54, the "instant specification does not demonstrate that nucleic acids that are at least 20, 50, 60, 80, 90 or 100 nucleotides in length that hybridizes to the nucleic acid of SEQ ID NO:76 or complement thereof, are amplified in primary lung tumors and in primary colon tumors compared to DNA isolated from normal controls, and would therefore, be useful in diagnosing said diseases." See page 5 of the instant Office Action. The Examiner further alleges that "the specification does not disclose the structure of the extracellular domain coding region within the nucleic acid that encodes the SEQ ID NO:76."

Applicants respectfully submit that the cancellation of Claims 34-36 renders the rejection of these claims moot.

Further, without acquiescing to the Examiner's position in the current rejections, Claim 33 has been amended so it does not claim the extracellular domain of the nucleic acid

sequence of SEQ ID NO: 76. Accordingly, Applicants respectfully submit that the rejection to Claim 33 is moot.

Without acquiescing to the Examiner's position in the current rejections, Applicants have amended Claim 48 to recite, "An isolated nucleic acid molecule consisting of an at least 20 nucleotides fragment of the nucleic acid sequence of SEQ ID NO:76, or a complement thereof, that specifically hybridizes under stringent conditions to ...." Therefore, as amended, Claims 48 (and, as a consequence, those claims dependent from the same) does not claim any variants of SEQ ID NO:76, but only claims a fragment of SEQ ID NO:76, or complement thereof. Accordingly, Applicants respectfully submit that since the specification is enabling for the nucleic acid of SEQ ID NO:76, the specification is also enabling for fragments of such that are usable as hybridization probes.

Based on the instant disclosure, which details how to make and use the claimed nucleic acids and the advanced knowledge in the art at the time of filing, one skilled in the art would know exactly how to make and use the claimed nucleic acids for the diagnosis of lung and colon cancer; for example, by using diagnostic methods based on hybridization to such amplified sequences.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the present rejections under 35 U.S.C. §112, first paragraph.

#### **Claim Rejections - 35 U.S.C. §102**

Claims 34-36 stand rejected and new Claims 48-54 are rejected under 35 U.S.C. §102(a) as allegedly being anticipated by Baker *et al.*, WO 200012708, published on March 9, 2000. In particular, the Examiner alleges that the subject matter of Claims 34-36 and 48-54 are not entitled to the October 29, 1999 filing date because "the parent application does not [disclose] a specific and substantial asserted utility or a well established utility for the subject of Claims 34-36 and 48-54."

Applicants respectfully submit that the cancellation of Claims 34-36 renders the rejection of these claims moot.

Furthermore, as discussed above, Applicants have amended Claim 48 to recite, "An isolated nucleic acid molecule consisting of an at least 20 nucleotides fragment of the nucleic

acid sequence of SEQ ID NO:76, or a complement thereof, that specifically hybridizes under stringent conditions to ...." Therefore, as amended, Claims 48 (and, as a consequence, those claims dependent from the same) does not claim any variants of SEQ ID NO:76, but only claims a fragment of SEQ ID NO:76, or complement thereof.

Accordingly, Applicants are entitled to an effective filing date of October 29, 1999 for Claims 48-54, and hence, Baker *et al.* is not prior art under 102(a) since its filing date is after the effective priority date of this application. Therefore, Applicants respectfully request that rejection to Claims 48-54 be withdrawn.

#### **Claim Rejections Under 35 U.S.C. §101**

Claims 46-47 are rejected under 35 U.S.C §101 allegedly because "the claimed invention is directed to non-statutory subject matter."

Without acquiescing to the Examiner's position in the current rejections, and without prejudice to further prosecution of the subject-matter in one or more continuation or divisional applications, Applicants have amended Claim 46 to recite "an isolated host cell." Thus, the claimed cells are distinguished over cells in nature. Hence, Applicants respectfully request reconsideration and withdrawal of the present rejection.

#### **Claim Rejections - 35 U.S.C. §102**

Claims 48-54 are rejected under 35 U.S.C. §102(a) as allegedly being anticipated by Strausberg (Accession No. BE782249, October 20, 2000) or by Ansorge *et al.* (Accession No. AL050202, February 18, 2000).

As discussed above, Applicants have amended Claim 48 to recite, "An isolated nucleic acid molecule consisting of an at least 20 nucleotides fragment of the nucleic acid sequence of SEQ ID NO:76, or a complement thereof, that specifically hybridizes under stringent conditions to ...." Therefore, as amended, Claims 48 (and, as a consequence, those claims dependent from the same) does not claim any variants of SEQ ID NO:76, but only claims a fragment of SEQ ID NO:76, or complement thereof.

Accordingly, Applicants are entitled to an effective filing date of October 29, 1999 for Claims 48-54, and hence, Strausberg is not prior art under 102(a) since its filing date is after the effective priority date of this application.

Similarly, Ansorge *et al.* is not prior art under 102(a) since its filing date is after the effective priority date of this application.

Accordingly, Applicants respectfully request that rejection to Claims 48-54 be withdrawn.

### **Claim Objections**

Claims 38-40 are objected to as being dependent upon a rejected base claim.

As discussed above, Claim 33 has been amended so it does not claim the extracellular domain of the nucleic acid sequence of SEQ ID NO:76. Accordingly, Applicants respectfully submit that the rejection to Claims 33 is moot and request the Examiner to reconsider and withdraw the present objection.

### **CONCLUSION**

The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited. Should there be any further issues outstanding, the Examiner is invited to contact the undersigned attorney at the telephone number shown below.

Applicants expressly reserve the right to pursue any canceled subject matter in subsequent continuation, divisional or continuation-in-part applications.

Please charge any additional fees, including fees for additional extension of time, or credit overpayment to Deposit Account No. 08-1641 (referencing Attorney's Docket No. 39780-2830 P1C45).

Respectfully submitted,

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